

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION**

In re:

MDL No. 1953

Heparin Products Liability Litigation

Case No. 1:08hc60000

ORDER

This document applies to all cases.

Pending is defendants Baxter Healthcare Corp. and Baxter International Inc. (Baxter), Scientific Protein Laboratories LLC and Changzhou SPL Co. Ltd. (SPL), and American Capital, Ltd. (ACAS)'s Motion to Bifurcate Heparin Trials. (Doc. 440).

For the reasons that follow, defendants' motion is denied

Background

This multidistrict litigation is a products liability action arising out of the manufacture and sale by defendants of contaminated heparin. Plaintiffs allege that use of contaminated heparin caused a myriad of adverse allergic-type responses leading to serious injuries, and in some cases, death.

Heparin is a commonly used blood thinner. Heparin decreases the clotting ability of blood, thereby preventing formation of clots and stopping the growth of already existing clots. It has been marketed in the United States for nearly seventy years and is used in a variety of clinical settings, including during kidney dialysis and cardiac procedures, and for treatment or prevention of serious medical conditions, including pulmonary embolis and deep vein thrombosis. Over one million

multi-dose vials of heparin are sold per month in the United States. Baxter supplies about half of the heparin sold in this country.

In late December 2007, the FDA and Baxter received over 350 adverse event reports associated with the use of Baxter's heparin products. The FDA characterized this as a marked increase from the number of reports associated with heparin use normally received in a similar time period. The FDA determined that these adverse events were associated with Baxter Heparin contaminated with an unknown agent.

On January 17, 2008, Baxter recalled nine multi-dose lots, and on February 29, 2008, Baxter recalled all of its heparin single and multi-dose vials and HEP-LOCK flush products.

A period of intense effort to determine the nature and source of the contaminant ensued. This resulted in the discovery that Baxter Heparin's active pharmaceutical ingredient (API), which Baxter obtained from Chinese suppliers and incorporated into certain categories of heparin products, contained Over-Sulfated Chondroitin Sulfate (OSCS). OSCS is a synthetic compound with anticoagulant properties that acts as a heparin mimic.

Litigation followed in both state and federal courts. On June 6, 2008, the Judicial Panel on Multidistrict Litigation transferred federal heparin products liability cases to this court for consolidated pretrial proceedings.

Defendants' pending motion seeks to separate the issues of causation and liability in each of the individual MDL bellwether trials which the parties anticipate trying before this court. Defendants contend doing so will save court time, reduce costs, promote settlement, preserve their right to fair trial, avoid unfair prejudice to defendants, avoid jury confusion, and not unfairly prejudice the plaintiffs' presentation of their cases.

Plaintiffs oppose the motion, arguing that bifurcation is inappropriate because: 1) the risk of unfair prejudice to plaintiffs in presenting their cases outweighs any putative benefits from bifurcation; 2) bifurcation will not advance the goals of the bellwether process; 3) judicial economy favors a single trial of all the issues; and 4) issues of causation and liability are inextricably related and there will necessarily be overlap between the evidence. (Doc. 456).

Discussion

Federal Rule of Civil Procedure 42(b) provides, in part: "For convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims."

The decision to bifurcate is "within the sound discretion of the trial judge." *In re Beverly Hills Fire Litigation*, 695 F.2d 207, 216 (6th Cir.1982). "The piecemeal trial of separate issues in a single suit is not to be the usual course." *In re Bendectin Litigation*, 857 F.2d 290, 307 (6th Cir. 1988) (quoting Wright & Miller, 9C Fed. Prac. & Proc. Civ. § 2388 (1971 & Supp. 1987); *Chubb Custom Ins. Co. v. Grange Mut. Cas. Co.*, 2009 WL 3853178 (S.D. Ohio) ("Bifurcation is the exception to the general rule that disputes should be resolved in a single proceeding."). The party requesting bifurcation bears the burden of demonstrating that it is warranted. *Elec. Credit Union v. Nat. Fire Ins. of Hartford*, 2009 WL 3210348, *2 (S.D. Ohio 2009); Wright & Miller, 9A Fed. Prac. & Proc. Civ. § 2388 (3d ed.).

When deciding whether to bifurcate, a judge must consider several factors, including "potential prejudice to the parties, potential jury confusion, and the relative convenience and economy which would result." *In re Beverly Hills, supra*, 695 F.2d at 216. Ultimately, however, the issue(s) contemplated for a separate trial must be sufficiently "distinct and separable from the others that a trial of it alone may be had without injustice." *In re Sept. 11th Litigation*, 2007 WL 1965559,

*2 (S.D.N.Y.) (quoting *Gasoline Prods. Co. v. Champlin Ref. Co.*, 283 U.S. 494, 500 (1931)); see also *In re Bendectin Litigation*, *supra*, 857 F.2d at 309.

Defendants argue that the issue of causation is distinct and separate from liability. They contend that I should divide the bellwether trials into two phases. The first phase would address whether the plaintiff was exposed to contaminated heparin, whether that exposure caused that plaintiffs' injuries, and compensatory damages. The second phase would address the defendants' liability, punitive damages and any other legal issues.

Defendants claim this division will serve judicial economy, promote settlement, and prevent introduction of irrelevant and unfairly prejudicial evidence about the defendants' culpable conduct during the causation phase of the trial. By determining causation at the threshold, defendants argue, the court and parties can avoid presentation of a substantial amount of evidence relating to liability and reduce the time and costs related to pretrial disputes about the evidence.

Moreover, according to defendants, bifurcation will preserve juror objectivity on the causation question by deferring presentation of provocative or inflammatory evidence regarding defendants' conduct that is irrelevant to causation. Defendants maintain that bifurcation will not prejudice plaintiffs because they will have a complete opportunity to present relevant evidence during each phase of the trial.

Plaintiffs contend that the causation and liability issues are inseparable and there is considerable overlap of the evidence.

Specifically, plaintiffs assert that product identification evidence is relevant to both causation and liability. Such evidence includes the source of contaminated heparin, amount of contaminant in the defendants' heparin products, how and when the contaminated heparin reached the market and plaintiffs' healthcare facilities, and the subsequent FDA and CDC investigations. Plaintiffs argue

that they will be prejudiced if they are not allowed to present this complete picture to the jury. Moreover, they assert, because much of the same evidence and many of the same witnesses would be presented in both phases, bifurcation will prolong the overall process.¹

Plaintiffs' arguments are well taken.

While "bifurcation is improper if the issues are not separable," *Angelo v. Armstrong World Indus., Inc.*, 11 F.3d 957, 964 (10th Cir.1993), causation and liability are neither separate and distinct issues nor readily severable.

Defendants assert that plaintiffs' medical evidence is unlikely to establish causation, because the injuries claimed can occur in the absence of exposure to contaminated heparin and/or because other medical causes cannot be ruled out. However, defendants also argue that plaintiffs cannot show that they were even exposed to Baxter Heparin products, much less those that were contaminated.

If I were to bifurcate, plaintiffs would have to put on product identification evidence not once, but twice; first to prove causation and second to prove liability. *See Patten v. Lederle Labs.*, 676 F. Supp. 233 (D. Utah 1987) (denying motion to bifurcate causation and liability where proof on causation required introduction of evidence concerning nature of defendant's vaccine, its toxic properties and known actions of these toxins in the human body, and expert would be required to testify in both phases).

¹ Bifurcation also creates problems for jurors, especially if they are not aware the trial will occur in multiple phases. Arguably, they could learn and be asked about that fact during *voir dire*. But that might prejudice the plaintiffs, as jurors might decide in favor of the defendants to avoid having to sit through the second phase. If they are not told beforehand, and return with a plaintiffs' verdict, making them unexpectedly have to continue on would be, at best, unwelcome and probably burdensome. This is especially so if the parties need time between phases to prepare for the second round. The impact of bifurcation on jurors is a reason for bifurcating only when clearly appropriate.

Furthermore, the interests of judicial economy will not be served by bifurcation. Defendants contend that a decision in their favor on causation would obviate the need for a trial on liability, and as a result, I could forego deciding evidentiary disputes related to the liability phase, such as motions in limine and *Daubert* issues.

In many cases this might be so. But here, much of the evidence related to defendants' liability in this MDL is generic and will be the same in each case. A verdict for defendant on causation in one case will not dispose of the issue of liability in all cases and does not obviate the need to decide evidentiary disputes related thereto.

Circumstances here are quite unlike those in the cases defendants cite in support of bifurcation. There courts addressed general causation and disposed of litigation wholesale because the verdicts were binding on all plaintiffs.

For example, in *Bendectin, supra*, 695 F. 2d at 216, the court held a consolidated trial to address the general causation issue of whether Bendectin could cause birth defects when administered at therapeutic doses. Similarly, in *Beverly Hills, supra*, 695 F. 2d at 216, the universal general causation issue was whether aluminum wiring caused a fatal fire. Finally, in the bifurcated asbestos litigation cases, the question of liability was similarly tried on a consolidated basis, with the causation and damage issued reserved for each Plaintiff to prove his or her damages. THOMAS E. WILLGING, TRENDS IN ASBESTOS LITIGATION 104-07 (Fed. Jud. Ctr. ed., 1987).

In this case, however, defendants are not proposing a single, consolidated trial to dispose of the litigation wholesale. Rather, defendants propose bifurcating each bellwether trial into two phases. Even if this approach potentially might save time and money, it is not likely to have the cumulative effect that motivated bifurcation in the cases noted above.

In any event, for the bellwether process to be of any real use, jury verdicts as to all contested issues appear desirable. Use of jury interrogatories will enable the court and parties to determine the jury's precise rulings on multiple, if not always all issues.

Lastly, as many courts before me have, I find that any potential for prejudice to defendants can be avoided with appropriate limiting instructions. *See Hamm v. Am. Home Prods. Corp.*, 888 F. Supp. 1037 (E.D. Cal. 1995) (declining to exercise discretion to bifurcate issues of liability and damages, despite arguments that intermingling evidence on two issues could result in prejudice to defendant where any potential prejudice could be cured with limiting instruction); *State of Ohio ex rel. Montgomery v. Louis Trauth Dairy, Inc.*, 163 F.R.D. 500, 505 (S.D. Ohio 1995) (same); *Brown v. Advantage Eng'g, Inc.*, 732 F. Supp. 1163 (N.D. Ga. 1990) (same); *Campbell v. AcandS, Inc.*, 704 F. Supp. 1020, 1024 (D. Mont. 1989) (denying motion to bifurcate issue of causation from liability: "The court is confident that a jury armed with a proper set of instructions to be compiled by the court with the assistance of counsel, will be able to render a fair and impartial verdict with respect to each of the defendants.").

Conclusion

In conclusion, defendants have not demonstrated that the issues proposed for bifurcation are separable. Moreover, bifurcation would likely be prejudicial to plaintiffs due the added expense and time that would result from presentation of duplicative evidence. Likewise, any savings in time and expense to the court is speculative at best – a ruling in one case will dispose of that case on its own facts but will not bind other plaintiffs, and I will still need to address evidentiary issues with regard to liability. Finally, any potential for prejudice to defendants can be addressed through proper limiting instructions. Accordingly, the Defendants' motion is denied.

For the foregoing reasons, it is hereby

ORDERED THAT defendants' Motion to Bifurcate Heparin Trials (Doc. 440) be, and the same hereby is, denied.

So ordered.

s/James G. Carr
Sr. U.S. District Judge